



American Red Cross

National Headquarters

October 18, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jacob Disease (CJD) and New Variant Creutzfeldt-Jacob Disease (nvCJD) By Blood and Blood Products 64 Fed. Reg. 44739 (1999) [Docket No. 97D-0318) August 17, 1999]

Dear Docket Officer:

This letter is to provide public comments on behalf of the American Red Cross (ARC or Red Cross) concerning the Food and Drug Administration's (FDA or Agency) Draft Guidance for Industry published on August 17, 1999 (the Guidance). The Guidance provides recommendations for blood collection facilities and their consignees for precautionary measures to reduce the possible risk of transmission of Creutzfeldt-Jacob Disease (CJD) and new variant Creutzfeldt-Jacob Disease (nvCJD) by blood and blood products.

Red Cross, through its 37 Blood Services regions, supplies almost half of the nation's blood component transfusion needs. Red Cross has initiated efforts to comply with the Guidance and anticipates full compliance within the six month time frame recommended in the Guidance.

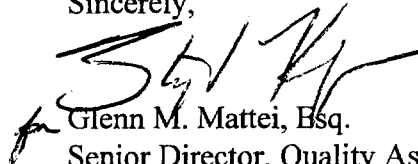
Red Cross would like to take this opportunity to indicate to the FDA our full endorsement of the public comment letter that has been submitted by the American Association of Blood Banks (AABB) including AABB's recommendation that the requirements associated with the theoretical risk factors to nvCJD should be implemented in a prospective manner only.

97D-0318

C10

On behalf of the American Red Cross, I would like to express my appreciation for the opportunity to submit our views. If you have any questions on this letter, please contact Anita Ducca, Director, Regulatory Relations at 703-312-5601.

Sincerely,

A handwritten signature in black ink, appearing to read "G. Mattei", with a stylized flourish at the end.

Glenn M. Mattei, Esq.
Senior Director, Quality Assurance and
Regulatory Affairs
Biomedical Services
American Red Cross

RECEIVED BY CROSS
MAIL ROOM
JAN 10 1964
SAC, NEW YORK
SAC, NEW YORK

THIS HAS BEEN
X-RAYED

Not Number